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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,886	04/18/2001	Stephen L. Mayo	A-65353-8/RFT/RMS/RMK	2783

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EXAMINER
KIM, YOUNG J

ART UNIT	PAPER NUMBER
1637	8

DATE MAILED: 02/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/837,886	MAYO ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-48,51 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-48,51 and 52* is/are rejected.

7)☒ Claim(s) *30-48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office Action responds the Amendment received on December 2, 2002 (Paper No. 8).

Objections & Rejections withdrawn

The objection of claims 4-20 for depending on a canceled claim, made in the Office Action mailed on August 9, 2002 is withdrawn in view of the Amendment received on December 2, 2002, canceling the claims.

Claim Rejections - 35 USC § 112

The rejection of claims 2-27, 29-48, and 50 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on August 9, 2002 is withdrawn in view of the Amendment received on December 2, 2002, canceling claims 2-27, and establishing proper antecedent basis for claims 29-48 and 50.

Claim Rejections - 35 USC § 102

The rejection of claims 21-26 under 35 U.S.C. 102(b) as being anticipated by Hardman (U.S. Patent No. 4,939,666, issued July 3, 1990), made in the Office Action mailed on August 9, 2002 is withdrawn in view of the Amendment received on December 2, 2002, canceling the claims.

Claim Rejections - 35 USC § 103

The rejection of claims 22 and 27 under 35 U.S.C. 103(a) as being unpatentable over Hardman (U.S. Patent No. 4,939,666, issued July 3, 1990) in view of Lee et al. (U.S. Patent No.

5,241,470, issued August 31, 1993), made in the Office Action mailed on August 9, 2002 is withdrawn in view of the Amendment received on December 2, 2002, canceling the claims.

Double Patenting

The objection of claims 2-20 under 37 CFR 1.75 as being a substantial duplicate of claims 29-50, made in the Office Action mailed on August 9, 2002 is withdrawn in view of the Amendment received on December 2, 2002, canceling duplicative claims 2-20.

The provisional rejection of claims 22-27 under 35 U.S.C. 101 as claiming the same invention as that of claims 22-27 of copending Application No. 09/714,357, made in the Office Action mailed on August 9, 2002 is withdrawn in view of the Amendment received on December 2, 2002, canceling claims 22-27 of the instant application.

The rejection of claims 2-5, 7-16, 28-32, 34-37, 39-44, 49, and 50 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15 of prior U.S. Patent No. 6,188,965, made in the Office Action mailed on August 9, 2002 is withdrawn in view of the arguments presented in the Amendment received on December 2, 2002. The rejection is withdrawn for claims 2-5, 7-16, 49, and 50 in view of their cancellation and the rejection is withdrawn for the remaining claims in view of Applicants' arguments.

The rejection of claims 2, 6, 17-20, 28, 29, 33, 38, and 45-48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 11, and 18-21 of U.S. Patent No. 6,269,312, made in the Office Action mailed on August 9, 2002 is withdrawn ***in part*** in view of the Amendment received on December 2, 2002. Specifically, the rejection is withdrawn for claims 2, 6, and 17-20 in view of their cancellation.

Rejections – Maintained & New Grounds

Claim Objections

Claims 30-48 are objected to for depending on proceeding claims.

Claim 32 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot be dependent on another multiple dependent claim. In the instant case, claim 32 is a multiple dependent claim which depends on claim 30 which is also a multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 32 has not been further treated on the merits.

Claims 32, 40, and 43 are objected to for the below reason.

A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 45-48 are product-by-process claims drawn to an optimized protein made by the method claims, a nucleic acid sequence encoding the optimized protein, an expression vector comprising the nucleic acid, and a host cell comprising the nucleic acid.

MPEP states that:

"A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence" (MPEP 2163(a)).

The specification discloses a few protein sequences (Gβ1, FSD-1) and their optimization. However, the claims are drawn to any and every protein derived from the claimed process. The claims fails to disclose a correlation between the function and structure of every protein, the nucleic acid encoding the protein, a vector comprising the nucleic acids, etc. Furthermore, there is no basis on which to search for what is being claimed. Because Applicants have not disclosed a sufficient number of species within the genus to which the claims are drawn, the claims lack in their written description as required under 35 U.S.C. 112, first paragraph.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 28, 29, 33, 38, and 45-48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 11, and 18-21 of U.S. Patent no. 6,269,312, made in the Office Action mailed on August 9, 2002 is maintained for the reasons of record.

In the Applicants' response received on December 2, 2002 (Paper No. 7), Applicants have indicated that a terminal disclaimer is being prepared for, "claims 28, 29, 33, 28 (*sic)*, and 45-48." It appears that the duplicate claim 28 is a typographical error and should be claim 38. Appropriate correction is required.

Because the Office has not yet received the terminal disclaimer and Applicants have not presented additional arguments, the rejection is maintained.

Claims 30, 31, 34-37, 39-44, 51, and 52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 7-10, and 12-17 of U.S. Patent No. 6,269,312 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Preliminarily, the above claims are dependent on base claims 28 and 29 which have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of the '312 patent.

Claims 30 of the instant application further limits its parent claim drawn to a method of optimizing a protein sequence by incorporating DEE (Dead End Elimination) process. Claim 1 of the '312 patent is drawn to a method of optimizing a protein sequence wherein the method requires DEE process. The difference between the claim of the instant application versus the claim of the '312 patent is the term "amino acids," used in the instant application versus the term, "rotamers" in the '312 patent. A section of the specification (also present in the '312 patent states that "each amino acid can be represented by a discrete set of all allowed conformers of each side chain, called rotamers" (column 5, lines 54-55). In other words the amino acids are represented by "rotamers." The specification of the '312 patent adds that, "[t]hus, to arrive at an optimal sequence for a backbone, all possible sequences of rotamers must be screened, where each backbone position can be occupied by either each amino acid in all its possible rotameric states, or a subset of amino acids, and **thus a subset of rotamers** (column 5, 55-60). The specification discloses no others "species" which would represent the "genus" of attributes of amino acids, other than the species of rotamers.

The current situation is analogous to that which was decribed in *In re Vogel* (164 USPQ 619, CCPA, 1970), wherein the court stated that:

"The correctness of this conclusion is demonstrated by observing that claim 10, by reciting 'meat' includes 'pork.' Its allowance for a full term would therefore extend the time of monopoly as to the pork process" (623).

In a similar manner, an allowance of the present claim drawn to a method using the amino acids would include the method using the rotamers of the '312 patent, thereby extending the time of monopoly to the method using the rotamers.

Because the specification of the '312 patent contemplates only one species within the genus of attributes of amino acids, the claim of the instant application is clearly indistinct over the claim of the '312 patent.

As to the remaining dependent claims 31, 34-37, and 39-44 of the instant application, their scope is identical to that of claims 4, 7-10, and 12-17 of the '312 patent.

Claims 51 and 52 of the instant application is drawn to a method of optimizing protein sequences wherein the difference between the claim of the instant application versus the claim of the '312 patent is the term "amino acids," used in the instant application versus the term, "rotamers" in the '312 patent. As explained above, the difference in their terms do not make the claims indistinct over the claims of the '312 patent.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so

as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

2/6/03

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
2/6/03